#12/Appeal Brief

Attorney's Docket No.: 06275-184001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Goran Marnfeldt et al.	Art Unit	: 3761
Serial No.	: 09/297,899	Examiner	: Joseph F. Weiss, Jr.
Filed	: May 10, 1999		
Title	: INHALATION DEVICE		

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BRIEF ON APPEAL

(1) Real Party in Interest

The real party in interest is the assignee, Astra Aktiebolag

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(2) Related Appeals and Interferences

There are no related appeals or interferences.

(3) Status of Claims

Claims 1-5 and 7-16 stand finally rejected. Claim 6 was said to be allowable if amended to overcome the rejection under 35 USC 112, second paragraph in the office action dated June 5, 2001. Claim 6 was so amended in the response filed on October 2, 2001, and the advisory action dated October 15, 2001indicated that the proposed amendments would be entered upon the submission of the Notice of Appeal (already submitted on October 2, 2001) and the Appeal Brief with requisite fees (this paper and fees included herewith). Accordingly the amendment will be entered upon receipt of this paper. The advisory action also recited that the "35 USC definity rejections of claims 1-16 would be resolved upon entry of the amendment." Accordingly, claim

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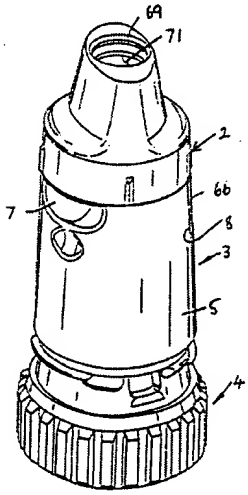
6 should be considered allowed and no longer subject to the final rejection upon receipt of this paper.

(4) Status of Amendments

Amendments filed on October 2, 2001 will be entered upon receipt of this paper, according to the advisory action dated October 15, 2001.

(5) Summary of Invention

The invention, as claimed in independent claim 1 and independent claim 16, is directed to inhalers that are used to inhale medicine in the form of a dry powder in order to have it delivered directly to the patient's lungs, e.g., in the treatment of asthma. Referring to Fig. 1, copied below on the left, the patient uses the inhaler by rotating knob 4 to advance a dose of powdered medicine into an airflow path (via an internal rotatable dosing unit 16 shown in Fig. 3 but not in Fig. 1), and by then placing mouthpiece 2 in the mouth and inhaling through the mouth to entrain the powder in the air flowing through the inhaler.



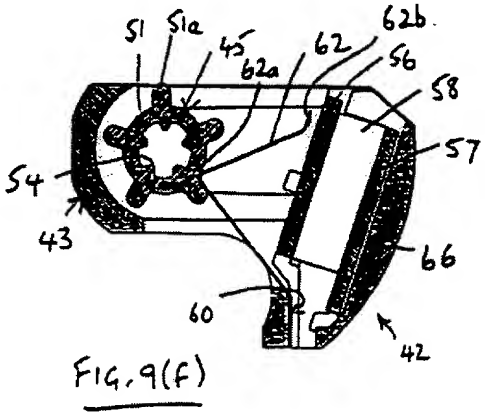


Fig. 9(f)

FIG. 1

The inhaler of claims 1 and 16 also includes an internal electronic dose counting unit, e.g., unit 42 shown in Fig. 9(f) copied above. The dose counting unit includes an electronic display (e.g., liquid crystal display 57, page 11, lines 2-3) that displays usage of the inhaler and an electrical circuit (e.g., printed circuit board 56 and the integrated circuit thereon, page 10,

lines 29-30) that counts doses and drives the electronic display, and a rotatable member (e.g., rotor 45) that is connected to the dosing unit so as to be rotatable therewith. The circuit also includes at least one switch with a contact element (e.g., contact element 62, which contacts a pad on PCB 56, page 11, lines 19-22). The rotatable member includes at least one cam surface (e.g., 51) with at least one cam (e.g., 51a). As the rotatable member rotates with the dosing unit, the cam physically contacts the contact element to move between the open position (e.g., as shown in Fig. 9(f)) and a closed position (e.g., with contact pad 62(b) touching a pad on PCB 56). The direct physical contact of the cam with the electrical contact provides a simple and very reliable switch activation.

Claim 16 also recites that the inhaler includes a housing (e.g., inhaler body 3) and that an inhalation channel member (e.g., 24 on Fig. 3), the rotatable dosing unit (e.g., 16 on Fig. 3), the rotatable member with the cam (e.g., 45), and the electrical circuit (e.g., 56) are all within the housing, that the electronic display (e.g., 57) is aligned with an opening (e.g., at window 66, shown in Figs. 1 and 9(f)) in the housing, and that a contact element of the switch is in the path of travel of the cam so as to be displaced between a first open position and a second closed position when a dose of medicament is provided to the inhalation channel. E.g., as shown in Fig. 9(f) above, as cam 51a moves with rotation, it will hit "knee" 62a of contact 62 and close the switch.

(6) Issues

Whether claims 1-5 and 7-16 are obvious under 35 USC 103(a) in light of Ambrosia U.S. Patent No. 5,687,710 ("Ambrosia") in view of Wolf U.S. Patent No. 5,505,195 ("Wolf").

(7) Grouping of Claims

Claims 1-5 and 7-16 stand or fall together.

(8) Argument

A. The Rejection

Claims 1 and 16 stand rejected under 35 USC 103(a) on the basis of Ambrosia, though Wolf is also relied upon in the rejection.

Ambrosia is cited for disclosure of an inhaler with a "rotatable dosing unit (22)," a "dose counting unit (580), comprised of a display (330), which is aligned in an opening of the housing which displays usage of the inhaler and which may be outfitted with an electrical circuit (col. 25, lines 23-29) for counting each dose of medicament provided to the inhalation channel and drive the dislpay [sic "display"] so as to provide an indication as to the usage of the inhaler ...." In point of fact, the counting unit 580 noted by the examiner is a mechanical one, and "display 330" is not an electronic display, but merely a transparent window that permits one to view indicia printed on a moving mechanical part. With respect to mechanical versus electrical counters, Ambrosia recites:

> Many types of mechanical and electrical counters are useful. A digital electronic counter can be disposed within the base or other areas of the device, and will require electrically conductive contacts which complete a circuit at some point in the dose loading operation; the characteristic of the required battery will be a factor in establishing a shelf life for the device. Presently preferred is counter mechanism 580, a decrementing mechanical counter that indicates the number of doses remaining to be dispensed. (Emphasis added).
>
> Counter mechanism 580 is comprised of the aforementioned first and second rotation prevention spring detents 224 and 232 on base 200, the aforementioned transparent plastic window 330 of adapter 320, a continuous counter ring 590, an intermittent counter ring 620 and a spring-biased pawl assembly 640. (Col. 25, lines 23-38) (Emphasis added).

This passage includes the entire discussion of electronic counters in Ambrosia. It is clear that mechanical counters are preferred, and it is clear that counter mechanism 580 is a mechanical counter that includes the listed mechanical parts.

The office action then purports to apply the claim language to Ambrosia in the following passage in which we have added brackets and emphasis:

> [T]he electrical circuit [1] would be understood to include a conventional switch arrangement comprised of contact elements arranged to have a first open position and a second closed position, when a dose of medicament is provided to the

> channel, a rotatable member (590) connected to the dosing unit, which is a cam (a rotating or sliding piece in a mechanical linkage) having a [2] camming surface (the surfaces of the various gear teeth 602/604/606, configured to rotate the dosing unit to provide a dose of medicament to the inhalation channel, where [3] the cam will be in physical contact with a contact element and is [4] capable of causing movement of a contact element respective of at least one switch from an open position to a closed position (see figs 67-82 & 93-104) or where the contact element is locatable within the path of travel of the cam for first and second position displacement, [5] but Ambrosia does not disclose the display being "electronic" and connected to the electric circuit and the electric counting mechanism as set forth by the applicant.

With respect to point [1] we note that there is no support for the statement that the switch would be a conventional switch; indeed, the secondary reference Wolf uses magnetically-activated reed switches. With respect to point [2], these camming surfaces are said by the examiner to be used to rotate the dosing unit and not to operate on the electrical switch contact as required by the claims. With respect to point [3], the cam of the recited camming surfaces do not act on an electrical contact as asserted; they instead act with respect to the dosing unit. With respect to point [4] the cam of the camming surfaces does not move any contact element, and there is no teaching or suggestion for somehow having these camming surfaces (i.e., the gear teeth) act on a contact element; the fact that they might hypothetically be capable of moving a switch contact element is irrelevant. With respect to point [5] the examiner admits that what he had called the display 330 (which really is merely a transparent window) is not an electronic display as required by the claims.

The examiner then relies on Wolf for disclosure of an electronic display: "However, Wolf discloses such electronic display (1035)."

B. The Claims Are not Rendered Obvious by Ambrosia and Wolf

Ambrosia's fundamental teaching is that a mechanical counter is preferred. In this respect, Ambrosia teaches away from the claimed invention.

While there admittedly is a disclosure of an electronic counter in Ambrosia, Ambrosia merely states that it can be disposed in the base or other areas and has contacts that complete a circuit at some point in a dose loading operation. (Col. 25, lines 23-32).

The combination of references fails to disclose or suggest the switch activation that is required by claims 1 and 16. Claim 1 recites a cam that is in physical contact with the contact element and causes movement of the contact element as a dose is delivered. Claim 16 recites that the contact element is located within the path of travel of the cam so as to be displaced between a first open position and a second closed position (i.e., open to closed or closed to open) when a dose of medicament is provided to the inhalation channel. As noted above, the direct physical contact of the cam with the electrical contact provides a simple and very reliable switch activation.

In the rejection, it is asserted that Ambrosia has a "cam ... having a camming surface (the surfaces of the various gear teeth 602/604/606) ... where the cam will be in physical contact with a contact element ... or where the contact element is locatable within the path of travel of the cam."

As is clear from Figs. 4 and 67 (copied below) and the discussion at col. 25, line 53 to col. 26, line 7, these gear teeth (602/604/606) are on the inside of the ring 590, which has indicia 600 printed on the outside (Fig. 67) so that they can be viewed through clear plastic window 330 (Fig. 4 at bottom left).

FIG. 4

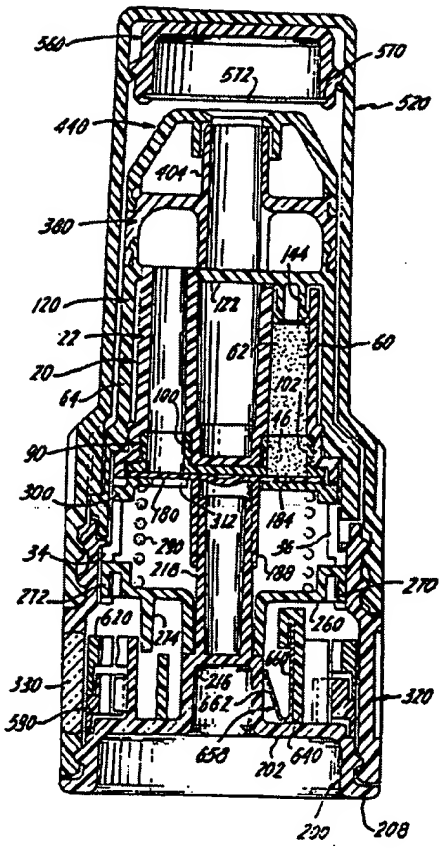
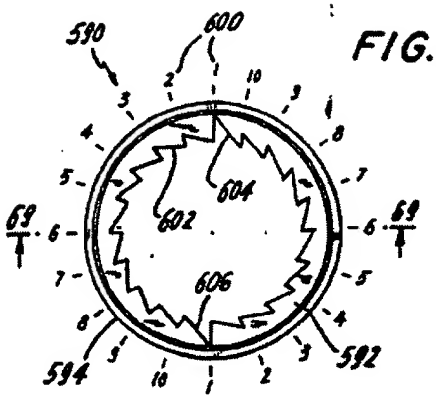
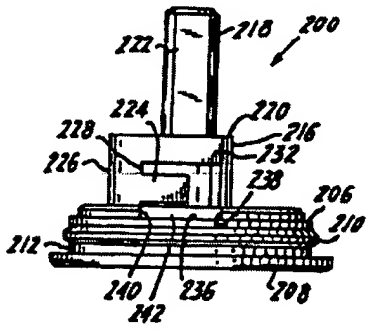


FIG. 67



Ambrosia describes these gear teeth 602/604/606 as being in physical contact with a rotation prevention spring detent 224 of base 200, which is shown in Fig. 27 copied below. (Col. 26, lines 3-7).

FIG. 27



There is absolutely no support for the statement in the office action that the "cam will be in physical contact with a contact element" or that the "contact element is locatable within the path of travel of the cam." The spring detent 224 merely prevents rotation. It is not an electrical contact, and is not even operably connected to the "display," which the office action says is transparent plastic window 330." (Col. 25, lines 35-36).

Wolf does not make up the deficiencies of Ambrosia and moreover teaches away from the invention. Wolf describes a device that is mounted on a conventional inhaler. The device includes a sheath 120 and an electronic housing 110 that connect to the inhaler. (Fig. 1) The sheath includes magnets 122 which rotate with the sheath when a dose is being supplied. The electronic housing includes "activation sensing elements 435 and 436" (e.g., reed switches) that open or close as the "magnet 122 (embedded in the wall of activation sheath 120 of Fig. 1) comes within the proximity of the magnetic field." (Col. 6, lines 9-19). These switches do not physically contact anything.

Thus the combination of references nowhere discloses or suggests a cam on a rotatable member that rotates with the dosing unit to "physically contact" and "move" an electrical contact or "displace" a contact "within the path of travel of the cam," as required by independent claims 1 and 16. Accordingly, independent claims 1 and 16 are patentable under 35 USC 103(a).

The remaining claims depend on independent claims 1 and 16 and are allowable with them.

Conclusion

For the foregoing reasons, it is respectfully submitted that the final rejection should be reversed and the application should be allowed.

The brief fee of $320 is enclosed. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: March 27, 2002

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Appendix of Claims

1. An inhaler for administering medicament by inhalation, comprising:

an inhalation channel;

a rotatable dosing unit which includes at least one dosing element for providing a dose of medicament to the inhalation channel; and

a dose counting unit which comprises an electronic display that displays usage of said inhaler, an electrical circuit for counting each dose of medicament provided to the inhalation channel and driving the display so as to provide an indication as to said usage of the inhaler, the electrical circuit including at least one switch which comprises a contact element that is movable between a first open position and a second closed position when a dose of medicament is provided to the inhalation channel, and a rotatable member connected to the dosing unit so as to be rotatable therewith, the rotatable member including at least one cam surface which includes at least one cam, each cam on each cam surface being configured, on rotation of the dosing unit to provide a dose of medicament to the inhalation channel, to be in physical contact with said contact element and cause movement of the contact element of said at least one switch between said first open position and said second closed position.

2. The inhaler of claim 1, wherein the electrical circuit includes a first switch which comprises a first contact element and a second switch which comprises a second contact element and the rotatable member includes first and second cam surfaces which each include at least one cam which is configured to cause movement of a respective one of the first and second contact elements from one said position to another said position.

3. The inhaler of claim 1, wherein the dosing unit includes a plurality of dosing elements and each cam surface includes a plurality of cams having the same angular spacing as the dosing elements in the dosing unit.

4. The inhaler of claim 3, wherein the plurality of dosing elements in the dosing unit and the plurality of cams on each cam surface are angularly equi-spaced.

5. The inhaler of claim 2,wherein the corresponding cams on the first and second cam surfaces are rotationally offset in relation to one another such that one of the first and second switches is one of opened or closed before the other.

7. The inhaler of claim 1, wherein each contact element is a resiliently-biased arm which includes a first part which rides on the respective cam surface and a second part which provides a contact pad.

8. The inhaler of claim 7, wherein the arm is resilient and configured such that the second part thereof which provides a contact pad moves at least partly laterally over a contact surface when the first part thereof rides onto and over a cam.

9. The inhaler of claim 7, wherein the arm includes a bend, the outer surface of which rides on the respective cam surface.

10. The inhaler of claim 1, wherein the dosing unit includes a shaft which includes a surface provided with one of at least one of an external or internal spline and the rotatable member includes a surface provided with the other of at least one of an external spline, the splines being engaged such that the dosing unit and the rotatable member in use rotate concomitantly.

11. The inhaler of claim 1, wherein the electrical circuit is configured to drive the display to display the number of doses used.

12. The inhaler of any claim 1, wherein the electrical circuit is configured to drive the display to display the number of doses remaining.

13. The inhaler of claim 12, wherein the electrical circuit is configured to drive the display to display intermittently the number of doses remaining when a predetermined number of doses or less are remaining.

14. The inhaler of claim 1, wherein the display is a liquid crystal display.

15. The inhaler of any of claim 1, further comprising a rotatable grip portion which is in use gripped by a user and when rotated in one sense rotates the dosing unit to proved a dose of medicament to the inhalation channel.

16. An inhaler for administering medicament by inhalation, comprising:

a housing member extending along a longitudinal axis, said housing member having an opening;

an inhalation channel member within said housing member extending substantially parallel to said longitudinal axis, said inhalation channel member having an inlet, a middle portion, and an outlet portion;

a rotatable dosing unit within said housing which includes at least one dosing element for providing a dose of medicament to said inlet of said inhalation channel member; and

a dose counting unit including a rotatable member connected to the dosing unit so as to be rotatable therewith, said rotatable member having a cam and being located adjacent to said middle portion within said housing, said dose counting unit also including an electronic circuit that includes a switch with a contact element located within the path of travel of said cam so as to be displaced between a first open position and a second closed position when a dose of medicament is provided to the inhalation channel, said circuit counting doses provided to said inhalation channel, said dose counting unit including an electronic display that is aligned with said opening in said housing, is connected to said electrical circuit and displays an indication of doses supplied to said inhalation channel of said inhaler.